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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,963	07/09/2003	Hani M. Agrama	59761	1262

7590

10/19/2005

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EXAMINER

LEWIS, KIM M

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/615,963

Applicant(s)

AGRAMA, HANI M.

Examiner

Kim M. Lewis

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/9/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action.

DETAILED ACTION

Response to Amendment

1. The preliminary amendment filed on 11/10/03 has been received and made of record. As requested, claims 31-36 have been added.

Drawings

2. The drawings were received on 11/10/03. These drawings are approved by the examiner.

Specification

3. The disclosure is objected to under 35 U.S.C. 132 because the applicant has added new matter to the specification after the filing dated of the application. Applicant is advised to cancel the new matter from the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 31-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to

Art Unit: 3743

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. More specifically, the specification as originally filed does not provide for "the outer surface of said adhesive layer substantially covering the inner surface of the said at least one fluid-filled cell", as recited in claim 31. Consequently, claims 32-36, which depend from claim 31, also rejected as depending from rejected base claim 31.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 4, 5, 9-12, 14, 16, 17, 21-24, 31, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,096,943 ("Maiwald").

As regards claim , Maiwald discloses a skin wound protector and inherently teaches a method for reducing pressure damage to skin of a person, the method comprising: determining at least one location on the person susceptible to pressure damage (constituted by the location on which the protector is placed); and adhesively securing a skin protective device (14) to the at least one location, the skin protective device comprising a substrate(18) having an inner surface and an outer surface, an adhesive layer (17) substantially covering the inner surface, and at least one fluid-filled

cell (constituted by dome-shaped portion) on the outer surface (col. 1, lines 13-18, col. 2, lines 5-18 and col. 3, lines 49-59).

As regards claim 2, note the removable layer in Fig. 7.

As regards claims 4 and 5, col. 1, lines 15-18 disclose that the dome can be filled with a medicated fluid, gel or ointment.

As regards claims 9, 10, 21, and 22 as can be seen from Fig. 8, the substrate is flat and has arcuate edges, thereby having a predetermined arcuate shape.

As regards claims 11 and 23, as can be seen from Fig. 8, the substrate contours the finger and is therefor inherently flexible.

As regards claim 14, Maiwald discloses a protector that anticipates applicant's presently claimed invention. More specifically, Maiwald discloses a substrate (18) having an inner surface to be positioned adjacent the skin of the person, and an outer surface; an adhesive layer (17) substantially covering the inner surface of said substrate for adhesively securing the substrate to the skin of the person; at least one fluid-filled cell (dome-shaped portions 16) on the outer surface of said substrate to cushion the skin of the person; and a removable layer (note Fig. 7 and col. 4, lines 27) on the adhesive layer to protect said adhesive layer prior to application to the skin of the person.

As regards claim 16, as can be seen from Figs. 3 and 4 of Maiwald, the dome-shaped portion defines an exposed outermost surface for the skin protector.

As regards claim 17, col. 1, lines 15-18 of Maiwald disclose that the dome can be filled with a medicated fluid, gel or ointment.

As regards claims 12 and 24, as can be seen from Fig. 8, the shape of the finger is retained while the protector is on the finger.

As regards claim 31, Maiwald discloses a protector that anticipates applicant's presently claimed invention. More specifically, Maiwald disclose a skin protective device (14) for reducing pressure damage to skin of a person and comprising: an adhesive layer (17) having an inner surface to be adhesively secured to the skin of the person, and an outer surface; at least one fluid-filled cell (16) having an outer surface to cushion the skin of the person, and an inner surface, the outer surface of said adhesive layer substantially covering the inner surface of said at least one fluid-filled cell; and a removable layer (Fig. 7 and col. 4, lines 27-28) on the inner surface of said adhesive layer for protection thereof prior to application to the skin of the person.

As regards claim 33, as can be seen from Figs.3 and of Maiwald, the dome-shaped portion defines an exposed outermost surface for the skin protector.

As regards claim 34, col. 1, lines 15-18 disclose that the dome can be filled with a medicated fluid, gel or ointment.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3743

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 3, 6, 7, 13, 15, 18, 19, 25-27, 29, 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maiwald.

As regards claim 3, , Maiwald fails to teach a plurality of fluid-filled dome-shaped portions in side by side relation. However, it has been held that duplicating the components of a prior art device is a design consideration within the skill of the art. *In re Harza*, 274 F. 2d 669, 124 USPQ 378 (CCPA 1960). Thus, it would have been obvious to one having ordinary skill in the art at the time of invention to duplicate the fluid filled dome of Maiwald and place them side by side in order to protect a wider portion of the skin.

As regards claim 6, Maiwald fails to teach the method of claim 1, wherein the adhesive layer covers at least 75% of the inner surface of the substrate. Absent a critical teaching and/or a showing of unexpected results derived from providing 75% of the inner surface of the substrate with and adhesive, the examiner contends that the percentage of the inner surface covered with the adhesive layer is an obvious design choice, which fails to patentably distinguish applicant's invention.

As regards claim 7, it is unclear from the disclosure of Maiwald as to whether or not the substrate has a uniform thickness. However, absent a c

As regards claim 13, Maiwald fails to explicitly teach that the protector is for use on the toe. However, it would have been obvious to one having ordinary skill in the art to place the protector on any area of the body that needs protection (e.g., toe).

As regards claim 15, Maiwald fails to teach a plurality of fluid-filled dome-shaped portions in side by side relation. However, it has been held that duplicating the components of a prior art device is a design consideration within the skill of the art. *In re Harza*, 274 F. 2d 669, 124 USPQ 378 (CCPA 1960). Thus, it would have been obvious to one having ordinary skill in the art at the time of invention to duplicate the fluid filled dome of Maiwald and place them side by side in order to protect a wider portion of the skin.

As regards claim 18, note the rejection of claim 6 above, which discusses the obviousness of covering 75% of the inner surface, the substrate of Maiwald with adhesive.

As regards claim 19, note the rejection of claim 7 above, which discusses the obviousness of providing the substrate of Maiwald with a uniform thickness.

As regards claim 25, note the rejection of claim 14 above, which substantially discusses the claimed structural elements of the claim. In further regard to claim 25, Maiwald fails to teach a plurality of fluid-filled dome-shaped portions. However, it has been held that duplicating the components of a prior art device is a design consideration within the skill of the art. *In re Harza*, 274 F. 2d 669, 124 USPQ 378 (CCPA 1960).

Art Unit: 3743

Thus, it would have been obvious to one having ordinary skill in the art at the time of invention to duplicate the fluid filled dome of Maiwald in order to protect a wider portion of the skin.

As regards claim 26, note the rejection of claim 6 above, which discusses the obviousness of covering 75% of the inner surface the substrate of Maiwald with adhesive.

As regards claim 27, note the rejection of claim 7 above, which discusses the obviousness of providing the substrate of Maiwald with a uniform thickness.

As regards claim 29, as can be seen from Fig. 8, the substrate contours the finger and is therefor inherently flexible.

As regards claim 30, as can be seen from Fig. 8, the shape of the finger is retained while the protector is on the finger.

As regards claim 32, Maiwald fails to teach a plurality of fluid-filled dome-shaped portions side by side. However, it has been held that duplicating the components of a prior art device is a design consideration within the skill of the art. *In re Harza*, 274 F. 2d 669, 124 USPQ 378 (CCPA 1960). Thus, it would have been obvious to one having ordinary skill in the art at the time of invention to duplicate the fluid filled dome of Maiwald and place them side by side in order to protect a wider portion of the skin.

As regards claim 35, note the rejection of claim 6 above, which discusses the obviousness of covering 75% of the inner surface, the substrate of Maiwald with adhesive.

Art Unit: 3743

11. Claims 8, 20, 28 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maiwald in view of U.S. Patent No. 4,952,618 ("Olsen").

As regards claims 8, 20, 28, and 36, Maiwald discloses the protector is constructed from plastic, a polymer. Maiwald fails to teach that the adhesive is a hydrocolloid adhesive.

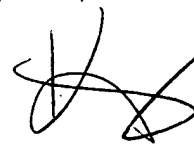
Olsen, however, discloses a hydrocolloid adhesive useful for wound dressings in that they absorb wound exudate. In view of Olsen, it would have been obvious to one having ordinary skill in the art to substitute the adhesive of Maiwald for the adhesive of Olsen in order to absorb wound exudate that flows from certain pressure sore.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3743

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis
Primary Examiner
Art Unit 3743

kml
October 16, 2005